DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Vitreon®
Docket No.: 98E-0849

DEC - 4 1998

#19

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,490,351, filed by Vitrophage, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Vitreon®, the medical device claimed by the patent.

The total length of the regulatory review period for Vitreon® is 2,729 days. Of this time, 603 days occurred during the testing phase and 2,126 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation on humans involving this device was begun: April 13, 1990.

   The applicant claims that the Investigational Device Exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on November 10, 1989. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on April 13, 1990, which represents the IDE effective date.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: December 6, 1991.

   FDA has verified the applicant's claim that the Premarket Approval Application (PMA) for Vitreon (PMA P910068) was initially submitted on December 6, 1991.

3. The date the application was approved: September 30, 1997.

   FDA has verified the applicant's claim that PMA P910068 was approved on September 30, 1997.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: David J. Josephic
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